

Food and Drug Administration  
Center for Food Safety and Applied Nutrition  
Office of Special Nutritionals

ARMS#

12844



2 - LABEL SAMPLE

**000001**

1. FLAG SURVEILLANCE <input type="checkbox"/> COMPLAINT <input checked="" type="checkbox"/> COMPLAINT SAMPLE				2. TYPE SAMPLE		3. SAMPLE NUMBER 98 - 651-955	
4. CF NO. 1719247		5. DATE COLLECTED 3-31-98		6. PRODUCT CODE 54FCE09		7. RESP FIRM M	
8. PROGRAM ASSIGN CODE 1. 03R201		9. HOURS 1. 6		10. RELATED SPL None		11. PC 2	
12. COLL NO. 110		13. SPLING DIST NSV		14. COLL DIST NSV		15. PRODUCT NAME AND IDENTIFICATION (Quote pertinent labeling including firm name and address) Capsules in brown plastic btls paper 1b18 in part "body right Weight Management Chinese XXX Fen-Chi Herbal Weight Control Supplement XXX 150 Capsules XXX Natures Sunshine Products, Inc. Spanish Fork, Utah 84660 XXX Contains the finest ephedra XXX, ginger XXX Take 2 capsules XXX one hour before breakfast. XXX Do Not Exceed 5 Capsules Daily XXX Promotional brochure reading in part "Nature's Sunshine Chinese Fen-Chi XXX body right Weight Management XXX Nature's Sunshine Products Spanish Fork, UT" Brochure on table near cash register of retail store approx 10 feet from product display shelf.	
16. REASON FOR COLLECTION (Indicate analysis needed & document assignment. Include CP No. and/or Assignment No. if applicable.) Complaint NSV-6563 CHECK FOR EPHEDRINE CONTENT & FOR CAFFEINE & OPIATE CONTENT				17. MFG CODES (Labels, pkg, shipping containers) "9107577" inv stamped on 1b1			
18. MANUFACTURER (Name, address & ZIP) Natures Sunshine Products Inc Spanish Fork, UT 84660				19. SHIPPER (Name, address & ZIP) Same as Mfr		20. DEALER (Name, address, ZIP & telephone) Sub-1: Sub-2:	
21. SIZE OF LOT FROM WHICH SAMPLED Sub-1 from remainder of Complainants btl Sub-2 from 3/150 btl lot 9107577 & 1/150 btl lot 9107537				22. EST VALUE \$72.00		23. RECEIPT ISSUED FDA472 FDA484 NONE X	
24. DATE SHIPPED & DOC REF Probably rec'd by retail store during wk of XXXX 3-23-98							
25. DESCRIPTION OF SAMPLE AND METHOD OF COLLECTION (Number and size of units, etc) Sub-1: previously opened btl containing 46 capsules from complainant. Sub-2: 1/150 capsule btl from retail store display shelf. Attached promotional brochure also obtained from retail store.							
26. HOW PREPARED Btls marked with sub #(1-2) & 1b18 ident as in block 27. Btls placed into a similarly ident paper bag & bag sealed as in block 28. Brochure ident as in block 27 & attached to white original of C/R.							
27. COLL IDENT ON PKG AND/OR LABEL "98-651-955 3-31-98 DED"				28. COLLECTOR'S IDENTIFICATION ON SEAL "98-651-955 3-31-98 Donald E. Dodson"			
29. SAMPLE DELIVERED TO U.S. Mail CHT				30. DATE DELIVERED 4-3-98		31. LAB SRL	
32. LAB W/SPLIT SAMPLE				33. ORIG C/R & RECORDS TO NSV			
34. IDS (STAINED)	a. INVOICE NO. AND DATE Not Available			b. SHIPPING RECORD (B/L, F/B, Waybill, Affidavit, etc) NO. AND DATE Shipped via UFS			
	c. OTHER PROS. C/R 3-31-98 signed by [redacted] clerk of retail store.			Complainant; & signed by [redacted]			
35. REMARKS (If additional space is needed, attach Form FDA 464, C/R Continuation Sheet) Note: Failed to include in Mr. [redacted] affidavit that he obtained the product from [redacted]  Please send copy of analytical results to complainant: [redacted]							
36. CONSUMER COMPLAINT NO. OR RECALL NO. NSV-6563		37. AMT. \$ N/C CRED. CD. C V B <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>		38. 704(d) SPL YES NO <input type="checkbox"/> <input type="checkbox"/>		39. COLLECTOR (Typed name and signature) Donald E. Dodson	

FORM FDA 464 (11/85) PREVIOUS EDITIONS MAY BE USED.

## COLLECTION REPORT

SAMPLE RECORD COPY

000002

PRODUCT LABELING

98651955  
2/21/98 LUSBY



LUS 2925



R597

**CAUTION:** This product contains ephedra. See your health care provider prior to use if: Pregnant or nursing, any medical condition exists, or when taking any prescription drug. Discontinue if nervousness, sleeplessness, loss of appetite, or nausea occur. Maximum ephedrine dose for healthy adults is 100 mg per 24 hour period, for no longer than 12 weeks. Improper use of this product may be hazardous to your health. Not intended for persons under 18. Not to be taken with other ephedra or ephedrine containing products.

KEEP OUT OF REACH OF CHILDREN

This bottle was sealed for your protection. Do not use if inner seal is missing or damaged.

Nature's Sunshine uses natural source materials in its products that are subject to color variation.

©1997 Nature's Sunshine Products, Inc.

Product of U.S.A.

96-651-19-  
E-31-98 DED  
SUB-1

body  
right™  
Weight Management

CHINESE 天然日光養生之道


**FEN-CHI™**

Herbal Weight Control Supplement  
400 mg (6.15 grains) each



- Burns fat
- Phytonutrients

150 CAPSULES



Stock No. 2925-3  
**NATURE'S SUNSHINE PRODUCTS, INC.**  
Spanish Fork, Utah 84660  
Founded in 1972 by the Hughes Family

**GUARANTEED PURE**  
Contains the finest ephedra (*Ephedra equisetina*) herb concentrate, ginger (*Zingiber officinale*) root, atracylodes (*Atracylodes ovalis*) rhizome, and hoelen (*Poria cocos*) plant in preservative-free capsules.

**RECOMMENDATION**  
Take 2 capsules one hour before breakfast. Take 2 capsules before lunch. Take one capsule between 3 and 4 p.m. **DO NOT EXCEED 5 CAPSULES DAILY.** Drink one glass (8 ounces) of Nature's Spring water with the capsules.

Drink 64 ounces of water per day on the Fen-Chi program. For maximum benefit, take Fat Grabbers with meals. Take Fen-Chi and Fat Grabbers for 4 weeks, rest for 1 week while using Garcinia-Chi with Fat Grabbers, then repeat the Fen-Chi program.

Each capsule contains 12.5 mg ephedrine.

9107377

000003

FLAG

Proj 12844

ANALYST WORKSHEET		1. PRODUCT Body Right capsules		2. SAMPLE NUMBER 98-651-955																
3. SEALS <input type="checkbox"/> NONE <input checked="" type="checkbox"/> INTACT <input type="checkbox"/> BROKEN		4. DATE REC'D 8/19/98	5. RECEIVED FROM [REDACTED]	6. DISTRICT OR LABORATORY SEA-DO																
7. DESCRIPTION OF SAMPLE One brown paper bag, officially sealed "98-651-955 3-31-98 Donald E. Dodson", containing 2 bottles of product id'd "98-651-955 3-31-98 DED" with sub number 1 and 2. Sub one is an open bottle containing 46 capsules, sub 2 is an intact bottle. Received at room temperature.																				
8. NET CONTENTS <input checked="" type="checkbox"/> NOT APPLICABLE <input type="checkbox"/> NOT DETERMINED <input type="checkbox"/> UNITS EXAMINED		DECLARED/UNIT AMOUNT FOUND % OF DECLARED		9. LABELING <input checked="" type="checkbox"/> ORIGINALS SUBMITTED <input type="checkbox"/> COPIES SUBMITTED <input type="checkbox"/> NONE																
10. SUMMARY OF ANALYSIS  container : opaque brown plastic bottle, 116mm high x 64mm diameter, with white plastic screw cap, 47mm diameter  labeling : commercially printed paper label glued to bottle  code : "9107577" stamped on bottle label  product : clear, colorless, conventionally shaped 2-piece hard gelatin capsules containing brown herbal powder, capsule standard size 0   Analysis : for ephedrine alkaloids by LIB 3996 Results : <table><thead><tr><th></th><th>mg/g</th><th>mg/cap</th></tr></thead><tbody><tr><td>ephedrine</td><td>22.8</td><td>11.9</td></tr><tr><td>pseudoephedrine</td><td>1.8</td><td>0.9</td></tr><tr><td><u>methyl ephedrine</u></td><td><u>trace</u></td><td><u>trace</u></td></tr><tr><td>total alkaloid</td><td>24.6</td><td>12.8</td></tr></tbody></table> <div>RECEIVED CLINICAL RESEARCH &amp; REVIEW/MSI 1199-451 98 SEP -2 11:24</div>							mg/g	mg/cap	ephedrine	22.8	11.9	pseudoephedrine	1.8	0.9	<u>methyl ephedrine</u>	<u>trace</u>	<u>trace</u>	total alkaloid	24.6	12.8
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11. RESERVE SAMPLE In original paper bag, officially sealed "98651955 8/27/98 JLBussey", 1 intact bottle, 1 open bottle, label removed id'd "98651955 8/20/98 JLBussey" with 26 remaining capsules, and one heat sealed plastic bag of remaining composite id'd "98651955 8/20/98 JLBussey". Returned to sample custodian.																				
12. a. ANALYST SIGNATURE (IF BROKE SEAL) JLBussey			13. WORK SHEET CHECK		a. BY Dan J. Moskowitz															
b.					b. DATE 8/28/98															
c.			14. DATE REPORTED 27 Aug 98																	